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| 10/578,248 | 02/27/2007 | Suk-Wah Tam-Chang | 028.0002-US00 | 3055 |
| 92049 | 7590 | 09/08/2011 | | |
| J.A. Lindeman & Co. PLLC 3190 Fairview Park Drive Suite 480 Falls Church, VA 22042 | | | EXAMINER SISSON, BRADLEY L | |
| | | | ART UNIT 1634 | PAPER NUMBER |
| | | | NOTIFICATION DATE 09/08/2011 | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|---|--------------------------------------|---|--|
| <i>Applicant-Initiated Interview Summary</i> | Application No. 10/578,248 | Applicant(s) TAM-CHANG ET AL. | |
| | Examiner Bradley L. Sisson | Art Unit 1634 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) Bradley L. Sisson, Primary Examiner. (3) Jeffrey A. Lindeman, Reg. No. 34,658.

(2) Suk-Wah Tam-Chang, co-inventor. (4) Stephen Bellum.

Date of Interview: 30 August 2011.

Type: ☐ Telephonic ☐ Video Conference
 ☒ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☒ Yes ☐ No.
 If Yes, brief description: Comparison of figures- instant application and FIG. 1 of Sauer et al.; draft claim.

Issues Discussed ☒101 ☒112 ☒102 ☒103 ☐Others
 (For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: Claim 16 & Draft claim (attached).

Identification of prior art discussed: US Patent Application Publication 2003/0003486 A1 (Sauer et al.).

Substance of Interview
 (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

See Continuation Sheet.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

| | |
|--|-------------|
| /Bradley L. Sisson/ Primary Examiner, Art Unit 1634 | Draft Claim |
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Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Co-inventor Tam-Chang provided an overview of the invention and provided statements that the claimed "nucleic acid complex" can be manufactured in a less-expensive manner as that required of the composition disclosed by Sauer et al. Co-inventor Tam-Chang provided a comparison of the invention as represented by their FIG. 1 with FIG. 1 of Sauer et al.

Examiner Sisson indicated that the aspect of cost is considered to be a secondary consideration and cannot be relied upon to overcome a rejection under 35 USC 102, but that it could be asserted in attempting to overcome a rejection of claims under 35 USC 103(a).

Examiner Sisson, indicated that in addition to distinguishing the claimed invention over the prior art, applicant must also overcome issues of utility (35 USC 101), written description and enablement (35 USC 112, first paragraph).

Examiner Sisson directed attention to page 15, paragraph [0060], lines 6-8, which state: "Although a single sequence is described, it is understood that thousands of these sequences can be made and tested simultaneously in a gene expression assay." Examiner Sisson indicated that he construed the claims to encompass a virtually limitless number of nucleic acid sequences, that they are not required to be useful, and that the specification has not been found to set forth a sufficient number of useful sequences so to reasonably suggest that applicant, at the time of filing, had possession of the entire genus of "nucleic acid complexes" encompassed by the claims. Examiner Sisson indicated that he had applied the test of written description as set forth in the decision of *Alonso* 88 USPQ2d 1849 (Fed. Cir. 2008). Examiner Sisson indicated that a review of the record failed to find sufficient showing that applicant had possession of the claimed invention at the time of filing. Examiner Sisson indicated that applicant's statement at page 15 of the disclosure is an admission as to what applicant had possession of at the time of filing, and that a "single sequence" does not reasonably suggest possession (real or constructive) of the entire genus of "nucleic acid complex[es]" claimed. Examiner Sisson indicated that it appeared as though applicant was attempting to rely upon obviousness to satisfy the written description requirement, and that such reliance is not permitted (*University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

"Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.")

In response argument that the claimed "nucleic acid complex" can be synthesized without undue experimentation, Examiner Sisson indicated that the claims under consideration are not drawn to a method of making, but rather, are drawn to the actual compound/composition, which can be made by any method, without regard to cost or difficulty incurred, and that ease or difficulty of production does not overcome the requirements of a written description.

In response to statements by Mr. Lindeman and Co-inventor Tam Chang that the nucleic acids have utility, noting that they could be used in diagnosis, prognosis, quantitative measurement of nucleic acids, etc. (specification at page 2). Examiner Sisson indicated that the claims do not require that the "nucleic acid complex" be useful in any method/manner that meets the requirements of 35 USC 101. Examiner Sisson indicated that he considered satisfaction of the utility requirement to be a "lynchpin of patentability" and that suggested utilities found in the disclosure have not been read into the claims. (Narrowing limitations found in the specification cannot be inferred in the claims where the elements not set forth in the claims are lynchpin of patentability. In re *Philips Industries v. State Stove & Mfg. Co, Inc.*, 186 USPQ 458 (CA6 1975).)

In response to assertions by Mr. Lindeman that utility does not need to be cited in the claims, using acetylsalicylic acid (aspirin) as an example, Examiner Sisson noted that a compound and its properties are inseparable, and that the properties ascribed to a specific compound, such as acetylsalicylic acid, are inherent and do not need to be recited in the claim. Examiner Sisson noted that in contrast, the claims encompass a virtually limitless number of "nucleic acid complexes" whose properties are undefined. Examiner Sisson also noted that the claims also encompass nucleic acids that are yet to be discovered and proven useful.

Examiner Sisson noted that the instant application comprises a Sequence Listing which comprises representations of some 12 oligonucleotides, and that all of the oligo's are labeled as "Artificial Sequence," which is further defined as being "Synthetic." The inherent utility of "artificial" and "synthetic" sequences was discussed, and contrasted to nucleic acids that have utility in diagnosis, prognosis, and quantification, which were not found to be disclosed in the instant application.

Mr. Lindeman indicated that he will consider further clarifying the aspect of a "capture oligonucleotide," noting the definition provided at paragraph [0044] (page 11), of the disclosure. Mr. Lindeman indicated that the definitions provided at paragraph [0044] satisfy the written description requirement for the claimed "nucleic acid complex." Examiner Sisson noted that nucleic acids have as an inherent property the ability to "capture" any nucleic acid that is complementary (fully or partial complementary) to self, including hybridization to self, noting the stem-loop formation of the claimed complex. Examiner Sisson noted that by adjusting the hybridization conditions, e.g., lower temperature and higher salt concentrations, a nucleic acid will effectively "capture" nucleic acids that which is highly dissimilar.

Examiner Sisson indicated that by asserting that one portion of the "nucleic acid complex" has utility as a "capture" sequence does not necessarily distinguish that sequence from virtually any other sequence and does not necessarily satisfy the utility requirements.